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SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 07/704,565 05/22/91 BERGER 26890-CIP **EXAMINER** TOM M. MORAN PATENT DEPT., SYNTEX (U.S.A.) INC. 3401 HILLVIEW AVE. ART UNIT PAPER NUMBER P.O. BOX 10850 1202 PALO ALTO, CA 94303 DATE MAILED: 01/28/92

This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

•	n is made final.
*Alshortened statutory period for response to this action is set to expire	this letter.
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:	
Notice of References Cited by Examiner, PTO-892. Notice of Art Cited by Applicant, PTO-1449 (4) Notice of Art Cited by Applicant, PTO-1449 (4) Notice of Informal Patent Application, F Information on How to Effect Drawing Changes, PTO-1474.	orm PTO-152
Part II SUMMARY OF ACTION	i
1) Claims 1-57 are pendir	ng in the application.
Of the above, claims are withdrawn	from consideration.
2. Claims	n cancelled.
3. Claims	
4. PT Claims 1. 40-43, 45, 5	' ed.
5.2 Ctaims 2-39 44 46-57 are reject	ted
are object	ted to.
6. Claims are subject to restriction or election	•
7. This application: has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purp	oses. Core
8. Formal drawings are required in response to this Office action.	· · · · · · · · · · · · · · · · · · ·
9. The corrected or substitute drawings have been received on	1:84 these drawings
10. :The proposed additional or substitute sheet(s) of drawings, filed on has (have) been approve examiner; disapproved by the examiner (see explanation).	d by the
	. ·· . ·
11: I The proposed drawing correction, filed	
2 12: ☑ Acknowledgement is made of the claim for priority under. U.S.C. 119. The certified copy has □ been received: ☐ no	t been received
13. Since this application apppears to be in condition for allowance except for formal matters; prosecution as to the ments in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	s closed in
14. Other	•

EXAMINER'S ACTION



Serial No. 07/704,565

Art Unit 1202

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-52, drawn to compositions & use, classified in Class 546, subclasses 99, 100.
- II. Claims 53-54, drawn to cyclization, classified in Class 546, subclasses 99, 100.
- III. Claims 55-56, drawn to Alkylation, classified in Class 546, subclass 99, 100.
- IV. Claim 57, drawn to Intermediates, classified in Classes 540, 546, 548, various subclasses.

The inventions are distinct, each from the other because of the following reasons:

The compound groups are distinct as seen by their markedly different structure. The group I compounds have the tricyclic ring system. Group IV has its place a bicyclic heterocyclic bicyclic ring system.

Inventions I, II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, one could perform an internal cyclization of the aminomethyl (or R3-aminomethyl) acid chloride, or the carboxamide with the



Serial No. 07/704,565

Art Unit 1202

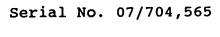
halomethyl. Or the imide could be reduced down to the lactam.

Because these inventions are distinct for the reasons given above and separate classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with W. Montgomery on 1-9-92 a provisional election was made with traverse to prosecute the invention of group I, claims 1-52. Affirmation of this election must be made by applicant in responding to this Office action. Claims 53-57 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Claims 1, 40-43, 45, 52 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim



Art Unit 1202

the subject matter which applicant regards as the invention.

- 1. "Acyloxy" of what structure? Does this include acyls of acids of Phosphorous? Sulphur? What does the stem of the acid look like?
 - 2. "Esterified" (e.g. in R⁵) with what?
- 3. The scope of claims 41-43, 45 cannot be deemed enabled.

 "A CNS disorder" embraces contradictory problems such as depression, seizures, amnesia, alcoholic blackouts, paralysis, Alzheimer's Disease, etc. Likewise, "A gastrointestinal disorder" covers e.g. the stomach producing too much and as well as too little acid. "A cardiovascular disorder" would mean that this drug could produce both vasoconstriction and vasocontraction; it could speed up and retard the pulse.

 "Cognitive disorder" would cover such diverse and unrelated disorders as depression Alzheimer's Disease, psychosis, dyslexia.
- 4. In addition, claim 41's emesis would appear to be covered by gastro-intestinal disorder.
- 5. In claim 40, "effective" for what (In re Fredricksen, 102 USPQ 35)?
- 6. Claim 52 is unclear and unsupported. There is no way of knowing what the range of this is. For all we know, the \mathfrak{F} -HT $_3$ receptor may play a role in all internal maladies of the body, even if that role is not yet elucidated. Further, this reads on situations where the 5-HT $_3$ receptors are to be blocked or





Serial No. 07/704,565

Art Unit 1202

stimulated, contradictory effects.

Claims 2-39, 44, 46-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Examiner Berch at telephone number (703) 308-4718.

RIMARY EXAMINER

120 - ART UNIT 122

Berch: ach

January 14, 1992